

PATENT
Attorney Docket No. 02508.0110-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Malin ERNEBRANT et al.) Group Art Unit: 1616
Application No.: 10/591,233) Examiner: Abigail L. FISHER
Filed: May 7, 2007) Confirmation No.: 9327
For: A MEDICAL SOLUTION, A)
METHOD FOR PRODUCING SAID) Via EFS-WEB
MEDICAL SOLUTION AND USE)
THEREOF)

Attention: Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY BRIEF

In reply to the Examiner's Answer mailed December 12, 2011, Appellant submits the following reply in response to the Examiner's arguments.

Appellant does not request an oral argument.

If any additional fees are required or if the enclosed payment is insufficient, Appellant requests that the required fees be charged to Deposit Account 06-0916.

REMARKS

This Reply Brief is being submitted in response to the Examiner's Answer mailed December 12, 2011 and the Corrected Examiner's Answer mailed January 19, 2012. The Corrected Examiner's Answer was prepared by the Examiner to include the Obviousness-Type Double Patenting Rejection, which had been omitted from the original Examiner's Answer. Appellant addressed the provisional double patenting rejection in the Appellant's Brief filed on September 22, 2011, requesting that this rejection be held in abeyance until the Examiner allows the pending claims. Appellant hereby repeats that request.

Claims 1-7, 11-14, 16, 17, 20, and 24 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,296,242 ("Zander") in view of U.S. Patent No. 6,309,673 ("Duponchelle"). Claims 8-10, 15, 18, 19, 21-23, 25, and 29-33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zander, Duponchelle, and further in view of International Patent Application Publication No. WO 01/89478 ("Linden"). In order to render a claim obvious, however, the Examiner must take into consideration all words in a claim and subsequently make "a searching comparison of the claimed invention - including all its limitations - with the teachings of the prior art." (M.P.E.P. § 2143.03; see also *In re Wada and Murphy*, Appeal 2007-3733, citing *In re Orchiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) and *CFMT v. Yieldup Intern. Corp.* 349 F.3d 1333, 1342 (Fed. Cir. 2003)). Contrary to the Examiner's assertion, the combination of Zander and Duponchelle, or Zander, Duponchelle, and Linden do not disclose or teach all of the elements of Appellant's claims. Nor do they guide one of

ordinary skill in the art to the claimed invention with any reasonable expectation of success.

As discussed in Appellant's Appeal Brief, the Examiner's interpretation of the claims vitiates elements of the claims. To traverse Appellant's argument, the Examiner's Answer relies upon a series of mischaracterizations of Zander and Duponchelle. (See Examiner's Answer at 14-18). Also, as noted below, the Examiner advances conclusory statements and fails to address the deficiencies of Zander and Duponchelle with respect to the elements of the claims. This failure to provide proper support further demonstrates that the combination of Zander and Duponchelle does not disclose Appellant's claims and that the § 103 rejection should be reversed.

For instance, the combination of Zander and Duponchelle fails to teach the claimed element "a first single solution comprising bicarbonate and carbonate in such proportions that a partial pressure of carbon dioxide in the first single solution is of the same order of magnitude as a partial pressure of carbon dioxide in the atmosphere." (See, e.g., claim 1). To teach the claimed element above, the Examiner asserts that since Zander recognizes that "the stability can be achieved by maintaining the CO₂ partial pressure of the liquid the same as atmospheric" and "that it must be ensured that no CO₂ escapes during storage, wouldn't this suggest to one of ordinary skill in the art to maintain the CO₂ partial pressure to be the same as atmospheric (i.e., no change in CO₂ content)?" (Examiner's Answer at 16). Thus, the Examiner appears to argue that the claimed element requiring the first solution to contain a specific proportion of bicarbonate and carbonate in order to have a partial pressure of CO₂ as that of the atmosphere, is inherent in Zander. This is incorrect.

While Zander may recognize that stability can be achieved if the CO₂ partial pressure of the liquid is the same as that of the atmosphere, Zander's teachings would not lead one of ordinary skill in the art to prepare solutions with specific amounts of bicarbonate and carbonate "in such proportions" that the CO₂ partial pressure is the same as that of the atmosphere. First, Zander fails to teach any particular partial pressure requirement of its alkaline solution. And, **all** of Zander's solutions contain a greater concentration of bicarbonate than carbonate. (Zander at Abstract). However, in order for the first single solution to be in equilibrium with the partial pressure of carbon dioxide in the atmosphere, **there must be a greater concentration of carbonate than bicarbonate in the first single solution.** (See, e.g., Examples 1-40 in the as-filed specification.) Moreover, Zander teaches that the pH of its alkaline solution is ~9.38-9.39. (Zander at col. 6, ll. 10-25). One of ordinary skill in the art would understand that the partial pressure of CO₂ in a solution with a pH of ~9.38-9.39 would **not** allow the solution to be in equilibrium with the CO₂ partial pressure of the atmosphere. Thus, Zander's teachings lead one of ordinary skill in the art away from the specific amounts of bicarbonate and carbonate "in such proportions" that the CO₂ partial pressure is the same as that of the atmosphere.

The Examiner further contends that the difference between the claimed final solutions and those of Zander/Duponchelle have not been demonstrated and "[i]n fact, the final solution suggested by Zander and Duponchelle possess the same ingredients and the same final pH." (Examiner's Answer at 17). This is incorrect.

While both references have an alkaline solution and an acidic solution, Zander's alkaline solution contains both carbonate/bicarbonate having a pH of ~9.38-9.39 and

Duponchelle's alkaline solution contains only bicarbonate in combination with sodium lactate, sodium chloride (no carbonate), and a suitable base at a pH of about 8.6 to 10. (Duponchelle at col. 7, ll. 3-18.) Thus, neither of the references teaches the claimed alkaline solution having a pH of 10.1 to 10.5. (See, e.g., claim 1.) Hence, even if one of ordinary skill in the art were to look to Duponchelle to modify Zander, their combination would not lead one of ordinary skill in the art to the claimed alkaline solution having a pH of 10.1 to 10.5.

Despite no such teaching in either reference, the Examiner nonetheless contends that the motivation to increase Zander's alkaline pH (to the claimed pH of 10.1 to 10.5) is based on Duponchelle's teaching that an elevated pH allows for a "solution that does not need a gas barrier." (Examiner's Answer at 7). Duponchelle's teaching is irrelevant, however, because Zander already teaches solutions without the need for a gas barrier. (Zander at col. 2, ll. 1-17.) Thus, one of skill in the art would not be motivated to modify Zander based on Duponchelle, even if Duponchelle taught a pH within the claimed range of 10.1 to 10.5.

In addition, Duponchelle's alkaline solution is based on a bicarbonate/sodium hydroxide combination not taught in Zander. Instead, Zander teaches a bicarbonate/carbonate alkaline solution. The Examiner has not clarified why one of ordinary skill in the art would simply add a base (i.e., sodium hydroxide) to increase Zander's alkaline solution without any motivation for doing so. Rather, one of ordinary skill in the art would have had no motivation to add sodium hydroxide to Zander's alkaline solution to increase its pH. One of ordinary skill in the art would understand that there is an advantage with starting from a mix of carbonate and bicarbonate in that

it allows a greater solubility of carbonate in comparison with bicarbonate, which, in turn, allows the pH to be kept high within the solution due to the amount of easily dissolved carbonate.

As a consequence, the partial pressure of CO₂ is slightly lower than that of the atmosphere, and may come close to atmospheric partial pressure of CO₂ when dissolution is completed. If, however, one of ordinary skill in the art were to add sodium hydroxide to bicarbonate in order to reach a higher pH, such as taught in Duponchelle, the resulting partial pressure of CO₂ is higher than atmospheric CO₂ partial pressure, and thus, CO₂ will escape from the solution and the final bicarbonate concentration obtained is not fixed. Thus, adding a base to Zander's alkaline solutions in order to increase its pH would lead to an alkaline solution with an unpredictable resulting bicarbonate concentration and pH. As a result, one of ordinary skill in the art would have had no motivation to combine Zander with Duponchelle for this purpose. See M.P.E.P. § 2143 (this is not merely a situation where "the substitution of one known element for another yields predictable results to one of ordinary skill in the art.") Therefore, not only does Duponchelle not teach an alkaline pH within the claimed range, but there is no reasonable expectation of success for utilizing, let alone a motivation for trying, the Duponchelle technology.

CONCLUSION

For the reasons given above, and those presented earlier in Appellant's Appeal Brief, the pending claims are allowable and the final rejection based on Zander and Duponchelle, or Zander, Duponchelle and Linden, should be reversed .

If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to Deposit Account 06-0916.

Respectfully submitted,

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Dated: February 3, 2012

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